K002974

OCT 11 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Emit® *tox* Acetaminophen Assay

I. Manufacturer and Contact Information:

Manufacturer: Syva Company - Dade Behring Inc.
20400 Mariani Avenue.
Cupertino, CA 95014

Contact Information: Paul Rogers
Syva Company
3403 Yerba Buena Road
San Jose, CA 95161-9013
Tel: 408-239-2000

II. Device Classification Name:

Acetaminophen test system has not been classified but fits with comparable assays as Class II.

III. Intended Use:

Emit® *tox* Acetaminophen Assay is a homogeneous enzyme immunoassay. The assay is intended for use in the quantitative analysis of acetaminophen in human serum or plasma.

IV. Device Description and Characteristics:

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Emit® *tox* Acetaminophen Assay is a homogenous enzyme assay intended for use in quantitative analysis of acetaminophen in human serum or plasma. The Emit *tox* Acetaminophen Assay and calibrators has been found to be equivalent to the predicate device: Emit® Acetaminophen Assay (K821379) with regard to intended use, assay sample, and overall performance characteristics.

Specificy: A panel of cross reactant drugs were spiked into a serum pool containing 50 µg/mL of acetaminophen. All tested cross reactants met acceptance criteria.

Comparative Analysis: The Emit® *tox* Acetaminophen Assay and calibrators showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in a correlation of 0.995 with a slope value of 1.01.

Precision: A Precision study was performed and the Emit® *tox* Acetaminophen Assay demonstrated acceptable within-run precision with coefficients of variation (%CV) ranging from 2.39% to 3.80% and acceptable total precision with coefficients of variation (%CV) ranging from 3.58% to 5.26%.

Spike Recovery: A spike recovery study was performed using 7 levels of spiked acetaminophen. The recovery ranged from 96% to 106%.

Sensitivity: The sensitivity level of the Emit® *tox* Acetaminophen Assay is <0.25µg/dL acetaminophen. This level represents the lowest measurable concentration of acetaminophen that can be distinguished from 0 µg/dL with a confidence of 95%.

Endogenous Interference: Endogenous interference due to bilirubin and hemoglobin were shown to give no interference at 60 mg/dL and 800 mg/dL respectively. The triglycerides showed no interference when tested with 10 lipemic samples ranging from 811 mg/dL to 1150 mg/dL.

High Sample Dilution: The range of recovery for the calculated high samples, diluted with Emit® Negative Calibrator, and tested on the Emit® *tox* Acetaminophen Assay was 95.1% - 97.5%.

Anticoagulants: The performance of the anticoagulants K_3EDTA, sodium citrate, sodium heparin,and potassium oxalate/sodium floride, as compared to serum had an average recovery, of 99.1%, 102.7%, 100.5%, and 102.1% respectively.

V. Substantial Equivalence:

In conclusion, Syva Company – Dade Behring Inc. considers the Emit® *tox* Acetaminophen Assay and Emit® *tox* Acetaminophen Calibrators to be substantially equivalent to the Emit® Acetaminophen Assay (K821379) and Emit® *tox* Acetaminophen Calibrators with regard to intended use, assay sample, and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 11 2000

Mr. Paul L. Rogers Jr.
Senior Manager, Regulatory Affairs
Syva Company – Dade Behring Inc.
3403 Yerba Buena Road
San Jose, California 95135

Re: K002974
Trade Name: Emit® tox Acetaminophen Assay
Emit® tox Acetaminophen Calibrators
Regulatory Class: II
Product Code: LDP, DKB
Dated: August 15, 2000
Received: August 17, 2000

Dear Mr. Rogers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K002974

Device Name: Emit® *tox* Acetaminophen Assay
Emit® *tox* Acetaminophen Calibrators

Indications for Use:

The Emit® *tox* Acetaminophen Assay is a homogenous enzyme immunoassay intended for *in vitro* diagnostic use in the quantitative analysis of acetaminophen in human serum or plasma. Acetaminophen is a widely used analgesic and antipyretic found in a number of over-the-counter and prescription products. When consumed in overdose quantities, acetaminophen may cause severe liver and kidney damage, or death. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002974

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)